Phase I/II Study of a Prime-Boost Schedule of Human GM-SCF Gene Transduced Irradiated Allogeneic Cancer Vaccines (Allogeneic Prostate GVAX ™) in Hormone-Naïve Prostate Cancer Patients.

Non-technical Abstract

Prostate cancer is the most common form of adult male cancer in the U.S., eclipsing lung cancer in incidence. In 1996, a new case of prostate cancer was diagnosed on average every three minutes in the U.S., with a new death from metastatic disease occurring every fifteen minutes. To date, radical prostatectomy and radiation therapy are currently recognized curative treatments of clinically localized prostate cancer. However, no curative systemic therapy exists for metastatic disease. A significant unmet medical need for more effective therapy still exists for advanced prostate cancer.

The proposed study is a phase I/II open-label, outpatient, single arm clinical trial. We plan to enroll twenty patients with progressive, micrometastatic prostate cancer after radical prostatectomy. The proposed protocol will evaluate the safety and efficacy of vaccination with lethally irradiated allogeneic prostate cancer cells (LNCaP and PC3) transduced with the human Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF) gene. The Allogeneic Prostate Cancer Cell Line Vaccine is composed of 2 equal cell doses of allogeneic prostate cancer cell lines (LNCaP and PC-3) genetically modified to secrete GM-CSF. Each vial is prepared to deliver 2.5×10^7 cells as a direct injectable in glycerol and human serum albumin. A retroviral vector is used to efficiently introduce the gene for GM-CSF into the allogeneic prostate cancer cell lines in this proposed trial. This immunotherapy approach to treat micrometastatic prostate cancer is based on findings in previous human clinical trials, that cytokine transduced tumor vaccines can induce antitumor and immunological responses in melanoma and renal cell carcinoma, as well as PSA responses in patients with micrometastatic prostate cancer. A trial identical to the proposed trial is currently ongoing at Johns Hopkins.